

REMARKS

This responds to the Office Action dated 6 August 2008. Applicants respectfully request reconsideration of the present application in view of the above amendments and the reasons that follow.

Claims 43, 56 and 72 have been canceled without prejudice or disclaimer. Claims 35-37, 39, 44, 49, 55, 63, 67, and 71 are currently amended. Support for the amendments is provided by at least Figures 7-14 and the related description of those figures at pages 11-13 of the present application. Claims 35-39, 41-42, 44-49, 51-55, 57-71, 73 and 76-77 remain pending in the application.

Claim Rejections – 35 U.S.C. § 102

The Examiner has rejected claims 35, 37, 38, 41-48, 55 and 57-62 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,662,681 to Nash et al. Applicants respectfully traverse the rejection.

Claim 35 as amended recites “deploying the anchor into the tissue puncture by advancing the anchor at least partially out of a distal end of the insertion sheath followed by inserting a portion of the insertion sheath between the anchor and at least one of the first and second surfaces of the multi-level nest to rotate the anchor into a deployed position.”

Nash discloses a closure device 20 that includes a sealing member or plug 30, an anchor member 32, a positioning filament 34, and a locking member 36. The closure device 20 is part of an instrument 100 for closing and sealing an opening. The instrument 100 also includes a tubular carrier 102, a bypass tube 104, and a tamper member 106. The carrier 102 has a

construction at its distal end such that the anchor member 32 is disposed longitudinally within the bypass tube 104 and laterally of the carrier tube 102 prior to the anchor being deployed. *See* col. 4, lines 40-50 of Nash. Figure 1 of Nash shows a proximal portion of the anchor member 32 in direct contact with the exterior surface of the carrier tube 102. There is no space or gap provided between the anchor member 32 and the carrier tube 102 when the anchor is in the undeployed position shown in Figure 1.

Nash discloses with reference to Figure 3, deploying the closure 20 using the instrument 100 (Figure 1) to seal closed a puncture in an artery wall. *See* col. 6, line 56 to col. 8, line 15. The carrier tube 102 is inserted into an introducer sheath (that was previously inserted into the puncture) with the anchor member 32 in the undeployed position shown in Figure 1. The carrier tube 102 is advanced until the anchor member 32 is moved distally beyond the distal open end of the introducer sheath and into a deployed position. The deployed position of the anchor member 32 is checked by retracting the carrier tube 102 relative to the introducer sheath. “This action causes the anchor member 32 to engage or catch on the distal end of the introducer sheath. . . . [wherein] resistance will be felt by the user to indicate appropriate deployment” *See* col. 7, lines 3-7 of Nash.

Nash fails to disclose use of the introducer sheath to “rotate the anchor into a deployed position” as required by claim 35. Nash is limited in its disclosure to using the introducer sheath to for a “check” that the anchor member 32 has already been deployed into the position shown in Figures 2-5. Thus, Nash fails to disclose “inserting a portion of the insertion sheath between the anchor and at least one of the first and second surfaces of the multi-level nest to rotate the anchor into a deployed position,” as required by claim 35.

Claim 37 as amended recites "providing a gap that extends between the carrier tube and the anchor in a direction that is transverse to the carrier tube, . . . [and] inserting at least a portion of the insertion sheath into the gap to rotate the anchor into a deployed position." Claim 44 as amended recites "the carrier tube including an outer surface, the outer surface including a first surface portion that is in contact with the anchor and a second surface portion that is adjacent to the anchor and recessed in the carrier tube relative to the first surface portion; [and] inserting at least a portion of the insertion sheath between the anchor and at least one of the first and second surface portions to rotate the anchor." Claim 55 as amended recites "the carrier tube including an outer surface, the outer surface including a first surface portion that is in contact with the anchor and a recess positioned adjacent to the anchor, the recess extending radially further into the outer surface of the carrier tube than the first surface portion; [and] inserting at least a portion of the insertion sheath into the recess to rotate the anchor."

Nash fails to disclose these limitations of claims 37, 44 and 55 for the same or similar reasons discussed above related to use of the introducer sheath to "rotate the anchor." Further, Nash fails to disclose "inserting at least a portion of the insertion sheath into the gap to rotate the anchor into a deployed position," as required by claim 37, "inserting at least a portion of the insertion sheath between the anchor and at least one of the first and second surface portions to rotate the anchor," as required by claim 44, or "inserting at least a portion of the insertion sheath into the recess," as required by claim 55.

Applicant submits that Nash fails to disclose every limitation of claims 35, 37, 44 and 55, and the claims that depend therefrom.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner rejected claims 36, 39, 49, 51-54, 56, 63-66, 71-73, 76 and 77 under 35 U.S.C. § 103(a) as being unpatentable over Nash et al. in view of U.S. Patent No. 5,814,073 to Bonutti. Applicants respectfully traverse this rejection.

Claim 49 as amended recites “an outer surface of the carrier tube including a recess that forms a gap between the anchor and the carrier tube in a direction that is transverse to the carrier tube; [and] moving a tip of the insertion sheath into the recess in the outer surface of the carrier tube to rotate the anchor.”

Claim 63 as amended recites “deploying the anchor by moving a tip of the insertion sheath into a recess in an outer surface of the carrier tube so that the tip is underneath the anchor before the anchor begins to move from an undeployed position, and distally advancing the insertion sheath in the recess rotates the anchor into a deployed position.”

Claim 71 as amended recites “the carrier tube including a recess in an outer surface of the carrier tube, the recess extending underneath the anchor; [and] positioning a tip of the insertion sheath in the recess so that the tip is between the carrier tube and the anchor before the anchor begins to move from an undeployed position, and distally advancing the insertion sheath in the recess rotates the anchor into a deployed position.”

Nash fails to disclose or suggest use of the introducer sheath to “rotate the anchor” as recited in claims 49, 63 and 71 for at least those reasons discussed above related to claim 35. Further, Nash fails to disclose “moving a tip of the introducer sheath into the recess in the outer surface of the carrier tube” (claim 49) or “distally advancing the insertion sheath in the recess” (claims 63 and 71). Nash is limited in its disclosure to using the introducer sheath for a “check”

that the anchor member 32 has already been deployed (*i.e.*, into the anchor member position shown in Figures 2-5).

Bonutti fails to remedy the deficiencies of Nash as it relates to claims 49, 63 and 71. Bonutti discloses an insert assembly 20 for positioning a suture anchor 22 relative to body tissue 24. The insert assembly 20 includes a tubular outer member 30 that defines a passage 32 and a leading end portion 62. The leading end portion 62 is movable between a closed position (*See* Figure 1) and an open position (*See* Figure 4). In the open position, the anchor 22 can be advanced distally out of the leading end portion 62 using an tubular inner member 54 to which the anchor 22 is mounted. As the anchor 22 is pushed through the open leading end portion 62, segments 88-94 of the open leading end portion 62 press against the side surfaces of the anchor thereby maintaining the anchor 22 in a desired orientation as the anchor 22 is moved into the body tissue 24. *See* col. 7, lines 12-24 of Bonutti. When the training end of the anchor 22 moves out of the open leading end portion 62, the tubular inner member 54 has moved into the open leading end portion 62. Continued movement of the *tubular inner member 54 rather than the leading end portion 62* can be used to change the orientation of the anchor 22 relative to the body tissue 24.

Bonutti fails to disclose or suggest using the tubular outer member 30 to “rotate the anchor” as required by claims 49, 63 and 71. The tubular outer member 30 does not perform any function relative to the anchor 22 during or after passage of the anchor through the open end portion 62 that results in rotation of the anchor 22. In contrast, Bonutti emphasizes the ability of the leading end portion 62 to maintain the anchor 22 in a given orientation while the leading end portion 62 is contacting the anchor.

Bonutti also fails to disclose or suggest “a recess that forms a gap between the anchor and the carrier tube in a direction that is transverse to the carrier tube,” or “moving a tip of the insertion sheath into the recess,” as required by claim 49. Bonutti also fails to disclose or suggest “moving a tip of the insertion sheath into a recess in an outer surface of the carrier tube so that the tip is underneath the anchor before the anchor begins to move from an undeployed position,” as required by claim 63. Bonutti further fails to disclose or suggest “the recess extending underneath the anchor; [and] positioning a tip of the insertion sheath in the recess,” as required by claim 71.

In view of the above, Applicants submit that Nash and Bonutti, alone or in combination, fail to disclose or render obvious every limitation of claims 49, 63 and 71, and the claims that depend from them. Applicants further submit that claims 36 and 39 are allowable for at least the reason they are dependent upon allowable base claims 35 and 37.

The Examiner also rejected claims 67-70 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,282,827 to Kensey et al. in view of Bonutti. Applicants respectfully traverse this rejection.

Claim 67 as amended recites “the anchor including an indentation that forms a gap between the anchor and the carrier tube, the gap being open along a proximal edge of the anchor; [and] positioning a tip of the insertion sheath in the gap before the anchor begins to move from an undeployed position, wherein distally advancing the insertion sheath in the gap rotates the anchor into a deployed position.”

Kensey discloses a closure 22 and an instrument 20 for inserting the closure 22 to seal an opening 24. An introducer sheath 28 (*See* Figures 15-20) is inserted through the opening and the

instrument delivers the closure 22 to the distal open end of the introducer sheath 28. An anchor, such as the anchor 32' shown in Figures 34 and 35, is advanced out of the distal open end of the introducer sheath 28 and orients into the deployed position shown in Figures 16-18. The instrument 20 is then withdrawn from the introducer sheath 28 until resistance is felt when the deployed anchor 32' catches on the distal end of the introducer sheath. *See* col. 5, lines 42-47. The anchor 32' and a sealing member 30 are then used to seal the opening 24. *See* col. 5, line 47 to col. 6, line 5.

There is no disclose or suggestion by Kensey of using the introducer sheath 28 to "rotate the anchor," as required by claim 67. Further, Kensey fails to disclose or suggest "the gap being open along a proximal edge of the anchor; [and] positioning a tip of the insertion sheath in the gap before the anchor begins to move from an undeployed position," as required by claim 67. Prior to deployment of the anchor 32' out of the introducer sheath 28 and into the deployed position shown in Figures 16-8, there is no interaction between the anchor 32' and the introducer sheath 28 that would meet these limitations of claim 67.

Bonutti fails to remedy the deficiencies of Kensey as it relates to claim 67 for at least those reasons discussed above concerning to the shortcomings of Bonutti. Applicants submit that Kensey and Bonutti fail to disclose or render obvious every limitation of claim 67 and the claims that depend from it.

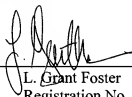
For at least the foregoing reasons, Applicants believes that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments

or suggestions, Applicant invites the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Applicants expressly disclaim all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

Respectfully submitted,

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